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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,636	11/25/1997	ELAZAR RABBBANI	ENZ-53(DIV-3	4642
28170	7590	05/31/2005	EXAMINER	
ENZO DIAGNOSTICS, INC. C/O ENZO BIOCHEM INC. 527 MADISON AVENUE 9TH FLOOR NEW YORK, NY 10022			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/978,636

Applicant(s)

RABBBANI ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 245-255, 258 and 261 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 245-255, 258 and 261 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

The instant Official action on the merits follows a petition to revive an abandoned application, which was approved on 14 March 2005. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 February 2005 has been entered.

### ***Status of Application/Amendment/Claims***

Applicant's response filed 17 February 2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 15 July 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 255 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last line of claim 255 refers to "said non-native intron". There is insufficient antecedent basis in the claim for this limitation, because the phrase "non-native" has been canceled from the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 245-255, 258, and 261 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 245, and those dependent thereon are drawn to nucleic acid constructs which comprise a nucleic acid sequence that encodes a non-eukaryotic polymerase that further comprises an intron, wherein said polymerase is expressed solely in a eukaryotic cell, and wherein said polymerase is capable of producing more than one copy of a nucleic acid sequence from said construct when introduced into a cell.

Applicants claim amendment of 14 October 2003 added the claim limitation pertaining to "non-eukaryotic polymerases", and "wherein said polymerase is expressed

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solely in a eukaryotic cell”. However, there does not appear to be support for these claim limitations in the specification as filed, and Applicants’ only reference to such support alleges that the amendments “are supported by the specification” (pg 14 of Applicants’ response). Applicants had previously disclosed and claimed only a polymerase comprising a non-native intron, but this is not considered to provide support for the phrase “non-eukaryotic polymerase...wherein said polymerase is expressed solely in a eukaryotic cell”, because they are clearly different entities with non-overlapping scope, and thus one of skill would not have been led from the former to the latter.

Furthermore, the same new matter issue is considered true in regards to claims 255 and 261, “...comprising a eukaryotic intron, which when in a eukaryotic cell, said intron is removed during processing and wherein said gene product or protein expressed from a gene product would be toxic to a non-eukaryotic cell in the absence of said non-native intron.” A review of the specification as filed does not reveal support for the genus of eukaryotic introns, or for the concept of toxicity to a non-eukaryotic cell in the absence of said non-native intron.

Should Applicants disagree, Applicants are invited to point out with particularity by page and line number where such support may exist. In the absence of any specific indication of support (other than “throughout the specification”), these limitations are considered to comprise new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 245-249, 252-254, and 254 is rejected under 35 U.S.C. 102(b) as being anticipated by Faruqi et al. (Virology (1991), 183(2), 764-8.)

The invention of the above claims is drawn to nucleic acid constructs which comprise a nucleic acid sequence that encodes a non-eukaryotic polymerase that further comprises an intron, wherein said polymerase is expressed solely in a eukaryotic cell, and wherein said polymerase is capable of producing more than one copy of a nucleic acid sequence from said construct when introduced into a cell, wherein the non-eukaryotic polymerase is selected from the group consisting of RNA polymerase, DNA polymerase, reverse transcriptase, and a combination thereof, or to the construct of claim 245, wherein said nucleic acid produced from said construct is selected from the group consisting of DNA, RNA, a DNA-RNA hybrid and a DNA-RNA chimera, or a combination of the foregoing, or to the construct of claim 253, wherein said DNA or RNA comprises sense or antisense, or both.

Faruqi et al. teaches a human hepatitis B virus polymerase that comprises introns. The construct of Faruqi is a viral construct which is taught as expressing a polymerase which then acts on the viral transcript to promote the expression of viral proteins, wherein said construct would comprise tRNA recognition and polymerase promoter sites.

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### ***Conclusion***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

  
**JAMES SCHULTZ**  
**PATENT EXAMINER**